

State of California
AIR RESOURCES BOARD

Final Statement of Reasons for Rulemaking
Including Summary of Comments and Agency Responses

PUBLIC HEARING TO AMEND THE ETHYLENE OXIDE ATCM

Public Hearing Date: May 21, 1998
Agenda Item No.: 98-5-2

I. GENERAL

On May 21, 1998, the Air Resources Board (ARB) conducted a public hearing to consider amendments to sections 93108 and 94143, Title 17, California Code of Regulations (CCR) — Ethylene Oxide Airborne Toxic Control Measure (Ethylene Oxide ATCM). One of the major modifications was to split section 93108 into two parts. Requirements for small commercial and non-commercial facilities are listed in Part 1 (section 93108). Requirements for large commercial facilities are set forth in Part 2, which was approved as section 93108.5. A major change in section 94143 was to add a test procedure for determining the concentration of ethylene oxide in water as well as to include of a test procedure for a particular type of ethylene oxide reclaiming technology that is in use at several California facilities. At the conclusion of the hearing, the Board approved the regulatory amendments as listed in Resolution 98-20. The Board's approved amendments included a number of modifications to the originally proposed text, reflecting suggestions made by the staff at the May 21, 1998 hearing.

The Board directed the Executive Officer to make the modified regulatory language available for public comment for a period of at least 15 days (in accordance with section 11346.8 of the Government Code). The Executive Officer was then directed to make modifications as may be appropriate in light of the comments received, and to present the regulations to the Board for further consideration if he determined that this was warranted.

The modified text of the amendments was made available for a 15-day comment period by issuance of a "Notice of Public Availability of Modified Text" which, together with a copy of the full text of the regulations with the modifications clearly indicated, was mailed on June 11, 1998, to each of the individuals described in subsections (a)(1) through (a)(4) of section 44, Title 1, CCR. The comment period began on June 11, 1998, and ended on June 26, 1998. No comments were received. The Executive Officer issued an Executive Order adopting the amendments with no additional changes from the text made available for 15-day comments.

An Initial Statement of Reasons (Staff Report) was prepared for the proposed rulemaking. The Staff Report was released to the public on March 26, 1998, and is incorporated by reference

herein. This Final Statement of Reasons (FSOR) updates the Staff Report by identifying and explaining the modifications that were made to the originally proposed text. The FSOR also contains a summary of comments received during the rulemaking process and the ARB's responses to these comments.

The Board has determined that the proposed regulatory action will not create any new costs or mandates to any local agency or school district. The Board did not anticipate an adverse economic or cost impact to private persons or businesses directly affected by the proposed action, as defined in Government Code section 11346.5(a)(9). The Board has determined that the proposed regulatory action will create some new costs or savings, as defined in Government Code section 11346.5(a)(6), to the State and districts. The cost will be associated with reviewing plans and reports, and inspecting sources to determine compliance with new recordkeeping and reporting requirements.

In December 1994, the United States Environmental Protection Agency (U. S. EPA) promulgated the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Sterilization Facilities (Ethylene Oxide NESHAP). The Ethylene Oxide NESHAP affects commercial sterilizers and fumigators and sets emission limits and other requirements. Some of these facilities are subject to the Ethylene Oxide ATCM and subsequent district rules. The Ethylene Oxide NESHAP differs significantly from the Ethylene Oxide ATCM. It applies to a small subset of the sources affected by the Ethylene Oxide ATCM, and its emission control requirements are less stringent than the applicable requirements of the Ethylene Oxide ATCM. Also, the Ethylene Oxide NESHAP contains more monitoring, recordkeeping, and reporting requirements than the Ethylene Oxide ATCM. The amended Ethylene Oxide ATCM will result in cost savings to the State and districts compared to implementing and enforcing both the existing Ethylene Oxide ATCM and the Ethylene Oxide NESHAP.

The amended Ethylene Oxide ATCM is designed to provide a single, easy-to-understand regulation that will continue to satisfy the State and federal requirements. All of the affected facilities are in compliance with the amended Ethylene Oxide ATCM emissions standards. Large commercial facilities will have to comply with the additional monitoring, recordkeeping, and reporting requirements. We believe that the action we have taken will result in cost savings to large commercial sterilizer facilities compared to implementing and enforcing both the existing Ethylene Oxide ATCM and the Ethylene Oxide NESHAP. These cost savings result from the elimination of duplicative requirements and from the elimination and streamlining of requirements in the Ethylene Oxide NESHAP. Also, there will be cost savings for small commercial and non-commercial facilities due to the streamlining of requirements and increased flexibility in the test procedures.

In preparing this regulatory proposal, staff evaluated the potential economic impacts on California businesses, enterprises, and individuals. The Board has determined that adoption of the proposed amendments will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. In accordance with Government Code section 11346.3, the Board has also determined that the

proposed regulatory action will not affect the creation or elimination of jobs within the State of California, the creation of new businesses or elimination of existing businesses within California, or the expansion of businesses currently doing business within California. An assessment of the economic impacts of this regulatory action can be found in the Staff Report.

Finally, the Board has determined that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulatory action was proposed or would be as effective and less burdensome to affected private persons that the action taken by the Board.

II. SUMMARY OF MODIFICATIONS

As discussed above, the Board approved the originally-proposed amendments to sections 93108 and 94143, and adopted section 93108.5, with various modifications suggested by the staff. This section summarizes the modifications made to the originally proposed regulatory text, and explains the rationale for the modifications. The modifications to the proposed amended sections 93108, 93108.5, and 94143, Title 17, California Code of Regulations (CCR), suggested at the Board hearing are shown in double underline regular text to indicate additions and *italicized strikeout* to indicate deletions.

A. **Part 1, Non-Commercial Sterilizers and Aerators and Commercial Sterilizers and Aerators using less than 2,000 pounds of Ethylene Oxide per 12 Consecutive Months.**

1. Reporting

Section affected: Section 93108 (d).

Change to read: "...available to the district upon request. Commercial sterilizers shall maintain copies of these reports on site for 5 years. This report shall..."

This change was made to satisfy the federally mandated requirement that all commercial facilities make available records of their annual ethylene oxide use for a period of five years.

2. Requirements

Section affected: Section 93108 (e)(3).

Make the following change: "the average concentration of ethylene oxide shall not exceed:"

This change was made to make the regulation language consistent with the language in the ARB Test Method 431 and to clarify that the average of the test runs should be used for

compliance determination.

3. Source Testing

Section affected: Section 93108 (h)

Change statement to read "Source testing shall be conducted according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district ~~in consultation~~ with the concurrence of the Executive Officer of the Air Resources Board."

This change was made to clarify that the ARB must agree to any source test method other than Method 431 or deviations from procedures in Method 431 if the test is being conducted for compliance purposes.

4. "NOTE: Authority cited" and "Reference"

Sections affected: Sections 93108 and 93108.5.

Change to read: "Sections 39600, 39650, 395610, and 39666, Health and Safety Code. Reference: Sections 39650, 39665, and 39666, Health and Safety Code, and 40 CFR, Part 63 Subpart O."

The addition of section 39650 was to indicate the additional citations in the Health and Safety Code that authorized staff to regulate toxic air contaminants. The (5) was deleted in the citation (395610) because it was a typographic error. We added "40 CFR, Part 63 Subpart O," to refer to the location in the Code of Federal Regulations that lists the federal requirements for commercial facilities.

B. Part 2, Commercial Sterilizers and Aerators using 2,000 pounds or more of Ethylene Oxide per 12 Consecutive Months.

1. Definitions

Section affected: Section 93108.5 (a)(1)

Change as follows: "Administrator means the Administrator of the United States Environmental Protection Agency ~~or his or her authorized representative (e.g., a district that has been delegated the authority to implement any portion of this part)~~ (or the implementing agency in accordance with any delegation of authority to approve alternatives from the U. S. Environmental Protection Agency)."

This change was made at the request of the U. S. EPA Region 9 staff to clarify delegation

of authority from the U.S. EPA Administrator.

2. Compliance Procedures

Section affected: Section 93108.5 (e)(2)(A)

Change to read "Source testing conducted for the purpose of demonstrating compliance must be according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district ~~in consultation~~ with the concurrence of the Executive Officer of the Air Resources Board, and the Administrator."

This change was made to clarify that the ARB and U. S. EPA must agree to any source test method other than Method 431, or deviations from procedures in Method 431, if the test is being conducted for compliance purposes.

Sections affected: Section (e)(2)(C)(i), (ii), and (iii).

Change "~~U.S. EPA Test Method 18, section 7.2~~" in each sentence to "Test Method 431 and subsection (f)(2)(A), (f)(2)(B), and (f)(2)(C)" respectively.

This change was made to simplify the testing by referring the tester to a procedure in the regulation that is the same as the procedure in the U. S. EPA test method.

3. Monitoring Requirements

Sections affected: Section (f)(2), Appendix 1(b)(4).

Change statement to read "For sources/facilities using ~~more than 20,000 pounds~~ 20,000 pounds or more of ethylene oxide per 12 consecutive months,".

This change was made to include a federal mandated requirements that facilities using exactly 20,000 pounds of ethylene oxide must comply with the monitoring requirements as well.

C. Test Method 431, Determination of Ethylene Oxide Emissions from Stationary Sources.

1. Sampling

Section affected: Section 94143, Page 1, Page 2, and Appendix A, page 6

Change sentence, "~~In the very recent past there have been explosions at several EtO sterilization facilities in other states.~~" to "There have been explosions at several commercial EtO sterilization facilities..." Delete the word "~~strongly~~".

This change was made to make the cautionary statement more clear.

2. Equipment

Section affected: Section 94143, Page 2

Change to read: "1. Gas Chromatography, flame ionization detector, photoionization detector, integrator, and columns."

This change was made to make the equipment section consistent with other sections of the method.

3. Determination of Ethylene Oxide Concentration at the Inlet of Control Units. Option 1, Inlet Estimation

Section affected: Section 94143 Appendix A, Page 6

Delete the sentence "~~The use of the inlet estimation technique is not allowed for sterilizer systems using water ring seal pumps (either flow through or recirculating) for chamber evacuations.~~" Add the sentence, "These estimation procedures may be used with sterilization systems using recirculating water ring seal pumps for evacuation of the chamber if the correction procedures outlined in Appendix B are followed."

This change was made in response to comments made by the U. S. EPA. It will allow greater flexibility in compliance testing while ensuring adequate accuracy.

4. Option 2, Inlet Measurement

Section affected: Section 94143 Appendix A, Page 6

Delete the sentence, "~~A loaded chamber must be used when performing compliance tests of sterilization cycles if using this inlet measurement option.~~"

The change was made to make the method language consistent with the language in the regulation.

5. Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units - Measurement Methods. Direct Interface Sampling Analysis

Section affected: Section 94143, Appendix A, Page 7

Delete the following: "~~For catalytic oxidation type control units, this procedure shall only be used if the sampling frequency is less than 2 minutes. For hydrolytic scrubber units, this procedure shall only be used if the sampling frequency is less than 1 minute.~~"

Add the sentence: "This procedure shall only be used if the GC sampling frequency provides at least 10 analysis points over the duration of the primary chamber evacuation."

Delete the following: "~~For cat-ox control units and For acid scrubber control systems, sampling will be conducted during the first evacuation and for the duration of any additional evacuation/wash periods (up to the point where aeration begins).~~"

Add the sentence, "Do not route the sulfuric acid scrubber exhaust back to the control unit as damage may occur to the catalytic bed." to paragraph beginning with "Excess EtO shall.....gas stream."

These changes were made in response to comments received during a public workshop. The changes recognize the need for flexibility in the testing procedure, and reflect sound testing practices in use now by special approval as alternative testing methods.

6. Procedures for Estimating Mass of EtO at the Inlet

Section affected: Section 94143 Appendix B, Page 9 and 10

Delete the last sentence of the first paragraph, "~~Use of flow through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO-ATCM.~~" Correct the spelling of the word reservoir in several places in this section. Change the definitions in the last six lines of section 4 on page 10 as follows: "...concentration of EtO in the pump reservoir after the exhaust test (µg/ml);" "concentration of EtO in the pump reservoir water before the exhaust test (µg/ml);" "volume of water in the reservoir after the exhaust test (ml);" and, "volume of water in the reservoir before the exhaust test (ml)". The word "~~after~~" is changed to "before" in the definition of Vol_{before}.

These changes were made to make the method language consistent with the language in the regulation, to correct typographical errors, and to respond to comments received during a public workshop.

7. Testing Procedures for Aeration Rooms

Section affected: Section 94143 Appendix C, Page 11

Delete the last paragraph of the section, "Testers must ...final results."

This change was made because the documentation of test probe placement as required by the paragraph was determined to be unnecessary.

8. Calculations

Section affected: Section 94143 Appendix F, Page 19

Change "scf~~m~~" to "scf" in the equation for " $W_t = C \dots$ " on the next to last line of the page.

These changes are corrections made in response to comments received during a public workshop.

9. Method Limitations - Inlet Estimation

Section affected: Section 94143 Appendix H, Page 23

Delete the sentence, "~~The inlet estimation technique should not be used with sterilization systems using water ring seal pumps, either flow through or recirculating.~~"

This change was made in response to comments made by the U. S. EPA. The change allows greater flexibility in compliance testing.

10. Method Limitations - Catalytic Oxidation

Section affected: Section 94143 Appendix H, Page 24

Delete the sentence, "~~Use of flow-through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO-ATCM.~~"

The change was made to make the test method language consistent with the language in the regulation.

11. Testing Procedures for Sterilizers With Joslyn Recovery Type Control Units - Identified points of EtO emissions from the Joslyn system include:

Section affected: Section 94143 Appendix K, Page 37

Delete the term "~~12/88~~ and word ~~are~~" from the last line of Paragraph 1. In paragraph 2, change the third sentence to read, "Moisture from the chamber collects in the separator and is normally discharged from the pump ~~several times per cycle~~ once per cycle at the beginning of the chamber evacuation."

These changes were made to reflect current EtO sterilant gas compositions (12/88 is no longer used), and to describe more accurately reclamation system operation.

12. Sterilization Exhaust

Section affected: Section 94143 Appendix K, Page 38

In paragraph 5, change the second sentence to read, "Collect the entire discharge of the heated chamber jacket in separate ½ hour samples for a 2 hour period starting ~~at the beginning of the chamber evacuation~~ 5 minutes before the end of the exposure stage." Delete the word "graduated" from the third sentence.

These changes were made to ensure that compliance testing samples captured all the EtO discharge, and to allow flexibility in the procedure.

13. Aeration Exhaust

Section affected: Section 94143 Appendix K, Page 38

In paragraph 3, make the following change to the third sentence: "Collect the entire discharge of the water ring seal pump ~~in separate 5 minute samples for a 1 hour period starting at the beginning of the aeration stage.~~ during the first 5 minute evacuation of the aeration stage." Delete the words "~~graduated, each of, and three~~" from the last paragraph.

These changes were made to ensure that compliance testing samples captured all the EtO discharge, and to allow flexibility in the procedure.

14. Method 431- EtO in Water

Section affected: Section 94143 Appendix L, Page 39 and 40

Delete "~~ethylene glycol~~" from the "ANALYTE" heading in the "measurement" column and from (1) in the "Reagents" section in "Referenced Methods."

Delete the last sentence beginning "Ethylene glycol, a ...and reported" in the section title "PRINCIPLE."

The change was made to make the method language consistent with the language in the regulation.

III SUMMARY OF PUBLIC COMMENTS AND AGENCY RESPONSES

The Board received five comment letters in response to the 45-day notice package for the May 21, 1998 Board hearing. These letters were from the Chemical Manufacturers Association, the South Coast Air Quality Management District (SCAQMD), 3M Health Care (a manufacturer of small ethylene oxide sterilizers), Gibson, Dunn and Crutcher LLP, and the U. S. EPA. Mr. Cliff McFarland of Gibson, Dunn and Crutcher LLP and Ms. Kathleen Steilen of Griffith MicroScience testified at the hearing for Griffith MicroScience.

The SCAQMD supported the proposed amendments to the Ethylene Oxide ATCM. We have summarized the other comments or recommendations and explained our action to accommodate the recommendation or explain our reasons for not making a change.

1. Comment: The Chemical Manufacturers Association commented that there is a new study that may indicate that health effects due to ethylene oxide exposure are not consistent with those listed in the health effects statements in the staff report.

Agency Response: This comment is outside the context of this rulemaking. The review of data for toxic air contaminant risk assessments is conducted by the Scientific Review Panel on Toxic Air Contaminants (SRP). At its December 1989 meeting, the SRP approved a process for responding to requests from the Air Resources Board to evaluate submittals of new scientific information. This procedure may be obtained from the Executive Officer of the Air Resources Board.

2. Comment: The South Coast AQMD indicated that their staff have been involved in the development of these amendments. They support the proposed amendments and respectfully request their adoption by the Air Resources Board.
3. Comment: Mr. Jack Veax, field representative for 3M Health Care, requested that the Air Resources Board work with 3M in a cooperative study to evaluate a new compliance testing procedure they have developed.

Agency Response: ARB staff committed to working with 3M. ARB staff has requested that 3M send the appropriate information for review and consideration. Staff will evaluate the data and make recommendations as to whether the procedure is acceptable.

4. Comment: Mr. Cliff McFarland and Ms. Kathleen Steilen of Griffith MicroScience requested that the Board suspend the regulation's requirement for control of the back draft valve emission stream because of safety concerns. Ms. Steilen requested that ARB staff and industry work together to study the safety issue, and make a recommendation to the Board as to how to handle back draft valve emissions.

Agency Response: During the development of the proposed amendments, staff held numerous telephone conversations with the affected commercial facility operators concerning backdraft valve safety and other issues. Staff also met with representatives of Griffith MicroScience and of the other commercial sterilizer/fumigator companies on July 27, 1997, to discuss safety issues and concerns related to the back draft valve control. No facility other than Griffith MicroScience expressed concerns over the safe operation of emission control equipment for the back draft valve gas stream.

Griffith MicroScience's two facilities in California (both in the SCAQMD) requested and were granted variances by the SCAQMD. The variances, granted in February 1998, allow Griffith MicroScience to disconnect the backdraft valve emission stream from the air pollution control devices until August 1999. We believe this allows sufficient time to develop technically feasible and affordable engineering solutions.

Deletion of the emission control requirements would allow unnecessary industry-wide increases in EtO emissions and consequent increase in risk of harm to public health.

The Board expressed concern about the safety issues raised by Griffith MicroScience and directed the staff to conduct several follow-up activities. First, the Board directed staff to survey the remaining commercial facilities to determine if any may require a variance and if so, to evaluate whether the existing variance procedure is appropriate to address the issue. Second, the Board directed staff to track and participate in efforts to develop alternative technology that could be used for controlling backdraft valve emissions. The Board felt these follow-up activities adequately addressed the safety issues. Therefore, no change was made to the regulation. In addition, Griffith MicroScience facilities have sufficient time to develop and implement solutions.

5. Comment: The U.S. EPA indicated that their initial approvability review of the ATCM is acceptable, and they are prepared to review and approve the ATCM after it is approved by the Board.

Agency Response: The ARB staff appreciate the effort made by the staff of U. S. EPA in reviewing and commenting on the draft Ethylene Oxide ATCM.